

AUG 26 2002

K022511

ATTACHMENT 7

510(k) Summary

July 25, 2002

Applicant: Aesthetic and Reconstructive Technologies, Inc. (AART)
3545 Airway Drive, Suite 108
Reno, NV 89511
(775) 853-6800 / FAX (775) 853-6805

Contact Person: Catherine Ripple
Consultant for AART, Inc.
(805) 239-1059

Proprietary Name: AART Calf Implant
Common Name: Silicone Carving Block
Classification Name: Elastomer, Silicone Block

Substantial Equivalence: The AART Calf Implant (Silicone Carving Block) is substantially equivalent in function, design, performance and materials to the Silimed Calf Implant marketed by Silimed LLC.

Device Description: The AART Calf Implants (Silicone Carving Blocks) are manufactured from a medical grade silicone elastomer that has been molded into various convex oval shapes. They are provided in two styles with dimensions varying in length, width, height and initial shape. The AART Calf Implant (Silicone Carving Block) is intended to be used for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary.

Intended Use: The intended use for the AART Calf Implant (Silicone Carving Block) is for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary. It may be used in body contouring to minimize muscular defects.

Predicate Device: The AART Calf Implant (Silicone Carving Block) is substantially equivalent in material, design, function, and performance to the Silimed Calf Implant marketed by Silimed LLC. of Crofton, MD. All products have identical intended uses and are offered in similar shapes and sizes.

Packaging: The AART Calf Implant (Silicone Carving Block) will be offered non-sterile. The implants will be individually packaged in an autoclavable peel pouch and labeled on the plastic side with appropriate identification for traceability. They will then be boxed in a SSB chipboard box along with a package insert and labeled for inventory and shipment.

Sterilization: The AART Calf Implants (Silicone Carving Blocks) are offered non-sterile. Recommended autoclave cycles are stated in the Package Insert which is included with each product.



AUG 26 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesthetic and Reconstructive Technologies, Inc.
c/o Catherine Ripple
5871 Lone Pine Place
Paso Robles, California 93446

Re: K022511

Trade/Device Name: AART Calf Implant
Regulation Number: 874.3620
Regulation Name: Ear, Nose and Throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIB
Dated: July 25, 2002
Received: July 30, 2002

Dear Ms. Ripple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

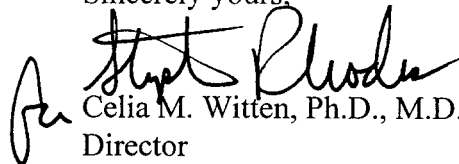
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Catherine Riple

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

ATTACHMENT 1

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510(k) Number (if known): K022511

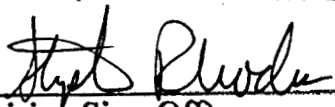
Device Name: AART Calf Implant (Silicone Carving Block)

Indications For Use:

The intended use of the AART Calf Implant (Silicone Carving Block) is for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary. It may be used in body contouring to minimize muscular defects.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022511

☒ Prescription Use
(Per 21 CFR 801.109)

OR

☐ Over-The-Counter Use

(Optional Format 1-2-96)